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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/941,154	08/27/2001	John R. Bianchi	RTI-112RIA	5282

7590 05/18/2007
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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

MAIL DATE	DELIVERY MODE
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05/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/941,154

Applicant(s)

BIANCHI ET AL.

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-13,30-33,35,39,56,60,61,64,67-69,71,72 and 74-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-13,30-33,35,39,56,60,61,64,67-69,71,72 and 74-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 04 April 2007 is/are: a) ☒ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Claims 37, 38, 51, 52, 70, and 73 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. **These claims have now been cancelled.**

Elections were made **without** traverse in the replies filed on October 27, 2005 and August 20, 2004. To summarize, Applicants elected Group I (product claims), Species D (Figure 8), allograft (set 1), cortical bone (set 2), PLA (set 3), mineralized (set 4), block (set 5), tongue with groove (set 6), and pin or rod (set 7).

Drawings

The replacement drawing sheets were received on April 4, 2007. These drawings are approved-in-part. The substitute sheets 1/20, 10/20, 17/20, 18/20, 19/20, and 20/20 have been accepted. However, the substitute sheet 8/20 has not been approved.

The drawings are objected to because they do not comply with Rule 84. Specifically, Figure 20G has multiple parts without projection lines indicating that the drawing is an expanded view and that the parts thereof are all part of the same device.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet,

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and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 74 is objected to because of the following informalities:

With regard to claim 74, on line 1, the terminology "implant comprises" is confusing because the transitional term "comprises" has already been used and it is not clear whether additional elements are being added or not. The Examiner suggests "implant comprises" to ---implant further comprises--- or ---implant includes--- in order to overcome this objection. Appropriate correction is required.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11, 12, 13, 30-33, 35, 39, 56, 60-61, 64, 67, 68, 69, 71, 72, and 74-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siebels et al (EP 0517030) in view of Coates et al (US 5,989,289). Siebels discloses an assembled bone implant made by assembling separate bone implant pieces together to form an implant by aligning bores of adjacent pieces. Next, Siebels introduces pins into the aligned bones to hold the implant pieces together; see Figures 1 and 2 and page 8 of the translation, first full paragraph and page 9 of the translation. However, Siebels fails to disclose making the implant pieces of cortical bone and mentions a preference for fiber-reinforced plastic (see page 3, last 4 lines of the translation) or carbon-fiber reinforced plastic (see the second full paragraph on page 6). Coates, however, teaches that it was known to make similar spinal implants out of allograft or autograft cortical bone because of its superior properties in vivo; see the abstract, column 2, line 33 to column 3, line 45, column 7, lines 18-43, and column 11, lines 42-61. Therefore, it is the Examiner's position that it would have been obvious to make the disks and pins of the Siebels implant out of cortical bone for the same reasons the Coates teaches doing the same.

Regarding claims 11, 12, and 39, Siebels meets the cleaning process limitations that are viewed as product-by-process limitations that do not clearly alter the structure of the product; see MPEP 2113 that is incorporated herein by reference. In particular, the cleaning process steps do not clearly suggest a product that would be cleaner than that disclosed by Siebels. Alternatively, one may view of the cleaning steps as having an effect on the final product structure. However, the Examiner asserts that any difference resulting from the process steps would at most result in only a slight

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difference between the claimed invention and the invention disclosed by Siebels. For this reason, the claimed invention is considered to be clearly obvious in view of Siebels and Coates.

Regarding claim 12, osteogenic material can be applied to the spaces of Coates including bone morphogenic protein (BMP) as claimed; see column 6, line 23 et seq.

Regarding claim 30, the spaces of Coates can have osteogenic material of demineralized bone and/or allograft bone applied to them such that the pin(s) of Siebels, which would be made into bone because of the teachings of Coates, would also have these materials applied to them. Therefore, all the pieces could be called a mineralized segment or a demineralized segment since each piece would contain at some of each material. Note that claim 31 allows a portion of the demineralized segment to mineralized.

With regard to claim 60, a similar product-by-process analysis applies to this pre-shrunk pins method step. The method step does not clearly result in a different product as that suggested by Siebels as modified by Coates.

With regard to claim 61, since bone is inherently flexible to some extent, the middle disks of Siebels as modified by Coates would meet the claim language calling for a flexible tissue.

Regarding claim 72, Coates teaches that it was known to use teeth or ridges for the vertebra-engaging surfaces; see Figures 12 to 20. Therefore, it is the Examiner's position that it would have been obvious to do the same with Siebels as modified by Coates.

Response to Arguments

Applicant's arguments filed April 4, 2007 have been fully considered but they are not persuasive.

Particularly, the Applicant's arguments follow the line of reasoning that it would not have been obvious to combine Siebels with Coates because Siebels wants easy assembly and Coates says that implants made of bone have been difficult to make.

In response, the Examiner asserts that Siebels desires easily assembleable disks that enable the surgeon to quickly assemble pre-manufactured disks into an appropriately sized implant. Coates, on the other hand, states that implants made with bone have had problems due primarily to their shapes and cancellous bone make-up. Coates discloses one example of a bone dowel that was not stable due to shape and cancellous bone make-up see the discussion of Cloward on column 3. Assembly of the implant pieces was not an issue. Coates solved the problems of the prior art by making the implant primarily of cortical bone and making the implant into a rectangular shape with vertebra engaging teeth and ridges to prevent migration. For this reason, the Examiner asserts that Coates is discussing an entirely different issue than that of Siebels.

The Applicant also argues that Siebels only means making implants out of plastic even when it states "solid disks can be manufactured of any biologically compatible material." This argument is not considered persuasive because the plain language of Siebels does not suggest such a limited understanding and because the use of plastics is considered to be mere exemplification or preference for making the device.

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Moreover, Coates provides the motivation to make the implant pieces of Siebels out of bone.

The Applicant also argues that there is no reasonable expectation of success for the combination of Coates with Siebels. However, the Examiner respectfully disagrees based upon his understanding of MPEP 2143.02. The fact that both the implant materials of Siebels and Coates can be machined to a particular shape and implanted to replace bones in the spinal column gives one a reasonable expectation of success.

With regard to the traversal of the claim 30 rejection and its discussion during the interview of May 1, 2007, the Examiner concluded that the claim 30 is still rendered obvious by Siebels and Coates because Coates teaches that mineralized segments can be coated with demineralized material. Since the demineralized segments of the claimed invention can be partly mineralized (see claim 31), it is the Examiner's position that the mineralized segments of Coates that are coated with demineralized material can be said to be demineralized segments as well.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Paul Prebilo", with a long horizontal flourish extending to the right.

Paul Prebilo
Primary Examiner
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